follow-up, all patients in each study arm remained free of any cardiac events. There were no target lesion revascularisations reported so far. 6 month follow-up examinations are expected to start in September 2002. At time of presentation, we will present the complete 6 month follow-up angiographic and IVUS data.
Conclusions: The FUTURE trial represents a pioneer experience demonstrating safety of the new Everolimus coated Challenge-Stent with a 100% procedural success rate and an uneventful in-hospital and 30-day follow-up in all patients. The 6 month follow-up data will be presented.

1006-184 Evaluation of a Tacrolimus-Eluting Coronary Stent With Nanoporous Ceramic Coating in Treatment of Native Coronary Artery Lesions: Phase I and II of the PRESENT Study

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Background: Drug eluting stents (DES)has recently emerged as one of the most promising techniques for interventional treatment of coronary lesions. Tacrolimus is an antiproliferative and antiinflammatory agent with proven efficacy in other therapeutical areas (transplant medication). The antiproliferative effect in coronary applications is selectively focused on smooth muscle cell activities rather than inhibition of endothelial cell proliferation. To evaluate both safety and feasibility of a Tacrolimus eluting stent, which utilizes a nanoporous aluminium oxide ceramic as drug carrier, the PRESENT study have been conducted.Methods and Results: The PRESENT Study is a prospective study, evaluating the ceramic coated coronary stent with and without Tacrolimus in treatment of native coronary de-novo lesions with 30 patients in each arm. Primary endpoint was 30-day safety defined as absence of MACE. Angiographic and IVUS follow-up was scheduled at 6 months after index procedure. The interim analysis after enrollment of 22 and 2 patients with DES and contol stent implantation, respectively, showed absence of in-hospital and 30-day MACE in each group; however, 3 target vessel revascularisations beyond the 30 day period in the group of DES were observed and the trial was halted (phase I). After modification of the stent design with increase in drug dosages loaded on the DES, the trial was restarted evaluating the bare ceramic coated stent and the modified high dose drug eluting stent in 30 patients each (phase II). To date, 24 patients in the high dose DES group has been enrolled without any adverse cardiac events after DES implantation. At time of presentation, complete procedural and 30 day follow-up data of the phase I and II patient population as well as 6-month angiographic and IVUS data will be presented.
Conclusion: The PRESENT trial demonstrates safety and feasibility of a new ceramic coated coronary stent with and without elution of Tacrolimus. The need of target vessel revascularisations in the low dose group (phase I) might suggest an inappropriate drug loading of the first stent version. Phase II with high dose Tacrolimus will clarify the efficacy of this concept in treatment of coronary lesions.

1006-185 Evaluation of the BiodivYsio Stent With Matrix HI Coating Designed for Local Drug Delivery in Coronary Arteries: A Randomized Trial

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Background: Stent coating integrating an active drug for local delivery is currently intensely investigated to prevent restenosis after coronary stent placement. Stent design, surface, and as shown in the ISAR-STEREO 1&2 trials, strut thickness have a significant impact on restenosis. The commercially available Bio*divYsio* stent is a thin-strut stent (90µm) with a phosphorylcholine coating (PC) with favorable long-term results as shown by the SOPHOS trial. The standard PC coating has been modified to allow local delivery of biomolecules (batimastat, angiopeptin and others). Goal of the present study was to evaluate the efficacy of the Bio*divYsio*stent with this Matrix HI polymer coating (MBIO) without an active drug, by comparison with the Guidant RX MultiLink (ML) which was the stent with the lowest restenosis rate in both ISAR-STEREO trials.
Methods & Results: Patients with symptomatic coronary artery disease (acute coronary syndrome in 38.7%) were randomly assigned to either the MBIO (n=142) or the ML (n=142). Baseline clinical and angiographic characteristics did not differ significantly between the 2 groups; vessel size was 3.00±.54 (MBIO) vs. 3.06±.50mm (ML), lesion length 13.2±6.9 vs. 13.1±6.9mm. Number of stents implanted (1.3±.9 vs. 1.3±.6), balloon/vessel ratio (1.16±.12 vs. 1.18±.13), and final %-diameter stenosis (5.6±9.7 vs. 5.0±8.9) did not differ significantly. Repeat angiography (performed in 80% of eligible pts.) revealed restenosis (>50% diameter stenosis) in 37.3% with MBIO and 17.3% with ML (p<.001), late loss was 1.17±.75 vs 0.98±.63mm (p=.04). After 1 year, target vessel revascularization was done in 22.5 vs. 13.4% (p=.04), the rate of death or myocardial infarction was not significantly different (4.9 vs. 4.9%).
Conclusions: In this randomized comparison, the Bio*divYsio*stent with Matrix HI polymer coating (without active drug) has less favorable results. As the restenosis rate for the standard PC-coated Bio*divYsio* was much lower in the SOPHOS trial (17.7%), these data suggest a negative effect of the Matrix HI polymer coating. This needs to be accounted for when designing and interpreting studies with this stent coating.

1006-186 Titanium Nitride-Oxide Coated Stent: Six-Month Angiographic and Intravascular Ultrasound Follow-Up

Christophe Caussin, Marie-Jeanne Alibelli, Meyer Elbaz, Martial Hamon, Gilles Grollier, Philippe Commeau, Bernard Lancelin, C.C. Marie Lannelongue, Le Plessis Robinson, France

Titanium nitride oxyde (Ti-NO) is biologically inert has an excellent biocompatibility exemplified by the lack of a redox and hydrolysis reaction as well as an absent complex metal ion-organic molecule binding formation. Ti-NO coated stent has significantly reduced neointimal proliferation compared to stainless steel stent in pigs. The aim of our study was to prospectively evaluate the feasibility and safety of a Ti-NO stainless steel coated stent (Helistent ®, Hexacath, France) in humans.
Inclusion criteria were a single lesion less than15 mm in length in a native coronary artery with a reference diameter between 3.0 and 4.0 mm eligible for PCI. Exclusion criteria were high-grade calcifications, ostial or bifurcation lesion, less than 72 hours acute myocardial infarction. Clinical follow-up was performed at one month and angiographic follow-up was systematically performed at six months. QCA and IVUS analysis were centralized.
133 patients were included in the study. 40 pts were selected for post implantation and six months IVUS analysis. Mean age was 62.4 ± 11.4 y. Prior history of diabetes was 19%, CABG :1%, PCI: 5%, MI 19%. Clinical presentation was unstable angina : 43%, stable angina: 23%, post MI : 17%, silent ischemia: 17%. ACC/AHA classification lesion was A:29%, B: 71%. Reference diameter with QCA analysis was 3.21± 0.36mm, MLD pre and post stent were 1.14± 0.32 and 2.99± 0.35mm. Post implantation IVUS reference diameter was 4.32+/- 0.45mm, reference area was 14.61+/-2.57mm2, stent symetry was 0.9+/-0.03 and stent lumen cross section area was 9.01+/-2.05mm2. Success rate implantation was 100%. In hospital events was one death due to per-procedure aortic dissection, one regressive stroke and two groin haematomas. At one month no subacute thrombosis, no TLR and no MI was observed.
In conclusion immediate and one month follow-up results are very promising. Six months angiographic and IVUS follow-up is ongoing, complete results will be communicated during the presentation.

POSTER SESSION

1007 Intravascular Ultrasound and Cardiovascular Disease

Sunday, March 30, 2003, 9:00 a.m.-11:00 a.m.
McCormick Place, Hall A
Presentation Hour: 9:00 a.m.-10:00 a.m.

1007-173 Incidence of Renal Artery Stenosis in 2,111 Patients Undergoing Coronary Angiography: A Model of Predictive Risk of Renal Artery Stenosis

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Background: Renal artery stenosis (RAS) is an important cause of hypertension and ischemic renal disease and should be identified in patients (pts) where possible. Data on the predictive risk of RAS at the time of coronary angiography for different patient profiles is lacking. Our aim was to determine the incidence of RAS in a large group of pts undergoing coronary angiography and to develop a model to determine the risk of RAS for any subgroup of pts. Methods: A total of 2111 consecutive pts were screened for RAS with a contrast injection in the descending aorta after the ventriculogram. Multiple risk factors were assessed. Results: RAS was present in 1% of pts without CAD and in 13% of pts with CAD. Independent risk factors for RAS in pts with CAD were age (Odds ratio (OR) 1.05/year, p<0.001), female sex (OR 1.91, p<0.001), peripheral vascular disease (PVD) (OR 2.32, p<0.001), cerebrovascular disease (CVD) (OR 1.60, p<0.05), 3 vessel disease (OR 3.14, p<0.001) and hypertension (OR 1.58, p=0.01). A model was developed utilizing these risk factors which enables the prediction of RAS in different patient profiles. An example is shown for males aged 60 with hypertension and CAD. Conclusions: RAS was rare in pts without CAD. In pts with CAD, there was a relatively high incidence of unsuspected RAS (13%). In pts with CAD and RAS there was a high incidence of other vascular disease. The incidence of RAS in pts with CAD can be predicted using the model developed and may aid in determining which pts should be screened.